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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): S14-US2

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on November 14, 2005

Signature: Michelle Hobson

Typed or printed name: Michelle Hobson

Application Number	Filed
10/084,826	October 24, 2001

First Named Inventor:

Art Unit	Examiner
1636	R. Akhavan

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [X] attorney or agent of record. Registration number 41,411
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

D Pasternak
Signature

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Telephone number

November 14, 2005
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of _____ forms are submitted.

CERTIFICATE OF MAILING PURSUANT TO 37 CFR § 1.8

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11/14/05 Michelle Hobson
Date Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Examiner: R. Akhavan
WOLFFE et al.	Group Art Unit: 1636
Serial No.: 10/084,826	Confirmation No.: 4340
Filing Date: October 24, 2001	Customer No.: 20855
Title: TARGETED MODIFICATION OF CHROMATIN STRUCTURE	

ARGUMENTS – PRE-APPEAL BRIEF CONFERENCE

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to OG Notice dated 12 July 2005, the following Arguments are presented concurrently with a Notice of Appeal and a Request for a Pre-Appeal Brief Conference. As required, the Arguments section presented herein is limited to 5 pages or less (pages 2 to 5 of this paper) and sets forth the clear legal and/or factual deficiencies of the rejections.

ARGUMENTS

The sole remaining rejection of claims 34-36 and 40-43 is alleged lack of written description (35 U.S.C. § 112, first paragraph). It is alleged that the genus of fusion molecules, particularly the components of the fusions, encompassed by the claims is unduly broad. It was asserted that possession of the "large number" of fusions encompassed by the claims has not been demonstrated, on the grounds that the specification only "discloses" a fusion polypeptide comprising a DNA-binding domain that recognizes a site in the VEGF gene and one of 5 enzymatic domains. (Final Office Action, page 3 last sentence). In addition, it was also asserted that Applicants arguments were not persuasive, in part, because the components were argued "separately."

At the core of this rejection is the misapprehension that in order to be adequately described, multiple examples of the claimed fusion proteins must be present and/or a laundry list of representative embodiments must be disclosed. While the Examiner acknowledges that there is no requirement that the "sequence/structure for all embodiments to be disclosed or known," what the Examiner is in fact requiring is exemplification or listing of multiple particular fusion proteins falling within the scope of the claims. (Final Office Action, page 7). Requiring multiple examples and/or laundry lists of possible fusion molecules in order to evince possession is factually and legally improper.

Legally, the assumption that satisfaction of the written description requirement necessitates that the Applicant exemplify and/or provide literal description of the structure of every possible fusion molecule encompassed by the claims is untenable. The written description requirement of 35 U.S.C. § 112, first paragraph should not be used to reject every broad, pioneering invention. Instead, each application must be judged on the particular fact pattern (disclosure, state of the art, *etc.*) with the underlying assumption that the specification as filed is presumed to satisfy the written description requirement. *See, e.g., In re Wertheim,* 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976).

Disclosure, much less exemplification, of multiple embodiments has never been a legal requirement of 35 U.S.C. § 112, first paragraph and, in fact, the Federal Circuit, the Board, the M.P.E.P. and the PTO's own Training Materials forbid such a test. [1]

Here, the as-filed specification contains pages upon pages of literal description of known enzymatic portions of chromatin remodeling complexes (*see, e.g.*, page 32-44) and known polypeptide and non-polypeptide DNA binding domains (*see, e.g.*, pages 30-32), along with disclosure of methods for making various types of fusion molecules (*see, e.g.*, page 44, line 18 to page 45, line 19 in the section entitled "Construction and Delivery of Fusion Molecules"). Moreover, detailed description is also present in the as-filed specification regarding the fusion molecules *per se* (*see, e.g.*, pages 30-32 for protein and non-protein DNA binding domains, pages 32-42 for enzymatically active portions of chromatin remodeling complexes, and pages 44-53 for fusion molecules comprising these components, particularly pages 44-45 for fusions comprising non-polypeptide DNA binding domains).

Thus, it is plain that Applicants were in possession of the claimed subject matter at the time of filing. To require literal description of actual, multiple embodiments is contrary to all established precedent.

Indeed, the Examiner has ignored the well-established rule that an applicant need not describe and preferably omits that which is not new. As set forth in the recent case of *Capon v. Eshhar* 76 USPQ2d 1078 (Fed. Cir. 2005), the Federal Circuit completely rejects the notion that the specification must describe information (*e.g.*, sequence data) that is either known or can readily be determined based on scientific facts (*Capon* at page 15, emphasis added):

> The "written description" requirement must be applied in the context of the particular invention and the state of the knowledge. The Board's rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization. ...
>
> The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same

[1] Indeed, as the Examples of PTO Training Materials on Written Description, including Example 14: "Product by Function," make clear, disclosure of a single species can readily satisfy the written description requirement for broad claims.

> way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.

The holding in *Capon* in particularly relevant to the instant case because the fact pattern in *Capon* is highly analogous to the fact pattern in the case at issue. In *Capon*, the Federal Circuit held that the precise sequence of a chimeric (fusion) antibody need **not** be described because the components were well known. Examiner's assertion in the instant case that Applicants are required to disclose multiple examples of particular fusion molecules, when each of the components (DNA binding domains that bind to particular target sites and enzymatic portion of chromatin remodeling complexes), as well as methods of making fusion proteins, were well known and described in the specification as-filed, is inconsistent with the requirements of the first paragraph of Section 112.

Contrary to the assertions in the Final Office Action, it is totally proper (and persuasive), as the Federal Circuit reiterated in *Capon*, to argue that each component of the fusion molecule was well known and described, methods for fusion are well known in the art and described in the specification and, hence, the claimed fusions are described. Applicants have clearly evinced possession of the components of the claimed fusion molecules and, accordingly, have satisfied the written description requirement.

Moreover, Applicants also amply describe that which is new, *i.e.,* using the claimed fusion molecules to modify chromatin in a target region. Thus, the disclosure of the specification as filed more than satisfies the written description requirement with the respect to the pending claims; and the notion that the specification provides "sufficient information in order for a person of skill in the art to construct such a product," but somehow fails to describe that product is completely at odds with not only *Capon* but with every case, rule and guideline relating to the written description requirement.

Thus, literal description is present in the original claims and description and the written description requirement has been satisfied. Applicants have shown possession of the claimed molecules at the time of filing – clearly and unmistakably. The written description inquiry need go no further than the claims and text of the specification itself, which clearly evinces possession of the subject matter of as claimed.

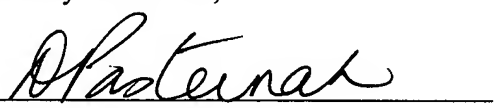
Applicants also note that the reliance on *Vas-Cath, Lockwood* and *Eli Lilly* is misplaced. The written description inquiry is fact-dependent. As such, the holdings in the various cases cited in the Answer are particular to the facts of those cases. In point of fact, the specification at issue in every case cited by the Examiner did not contain literal description of the claimed subject matter. As noted above, the facts and holding in *Capon* are much more relevant to the case at hand – disclosure of the particular fusion molecules is not required to satisfy the written description requirement when the components of the fusion molecule (and methods of making fusion molecules) were known and described. Applicants' specification contains precisely such literal disclosure and, accordingly, possession of the claimed fusion molecules has been established. Indeed, by disregarding the presumption of adequate description and the clear literal support in the specification set forth in all the case law, the rejection contravenes all established law, rules and guidelines.

In sum, the claimed compositions are described in the as-filed specification in such a way that a skilled artisan would clearly and unambiguously recognize that Applicants were in possession of the claimed invention at the time of filing. As such, the written description requirement is satisfied and Applicants respectfully request that this rejection be withdrawn.

For the reasons state above, Applicant respectfully submits that the pending claims define an invention that is novel, non-obvious, fully enabled and described by the specification. Accordingly, Applicant requests that the rejection of the claims be withdrawn, and that the application proceed to allowance.

Respectfully submitted,

Date: November 14, 2005

By: 

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